RÜSCH
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
FAX (603) 532-8211 or 6108

NOV 2 7 2001

K013266

510(k) Summary

1. **Submitter Name, Address, and Date of Submission.**

Miss Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-8211

Contact: Same as above

2. **Name of the Device, Common, Proprietary (if Known), and Classification.**

Classification Name: Tracheal Prosthesis

Common Name: Tracheal Bronchial Stent

Proprietary Name: Rüsch Polyflex Stent Kit

3. **Identification of the legally marketed device to which the submitter claims equivalence.**

The Rüsch Polyflex Stent is substantially equivalent to the Boston Scientific Ultraflex®, Schneider Wall Stent, the Cook Gianturco-Wallace Tracheobronchial "Z" Stent, and Bryan Dumon Tracheal Bronchial Stent-,Hood Tracheal Bronchial Stent, and Hood Westaby Stent

4. Description of the Device.

The Rüsch Polyflex Stent Kit consists of a medical silicone supported by a polyester core along with the components required to insert the device into the human body. These components consist of the Introducer Sleeve, the Stent Loader, Soft Positioner, and Blue Stopper.

This amendment changes the material of the Insertion accessories, adds indicator markings to the stent and provides for a non-sterile version.

5. Intended Use of the Device.

The indications for use for the Polyflex Stent Kit are as follows:

Airway complications such as anastomosis ans stenosis, Trachea-esophageal fistula, Stenosis of the central airways(such as the trachea and main bronchus), and Compression or strictures due to tumors (Trachea and main bronchus).

6. Summary of Technological Characteristics.

The following technological characteristics are the same as or equivalent to the predicate device, the Boston Scientific Ultraflex® and the Schneider Wall Stent. The primary material of the Rüsch Polyflex Stent is medical grade silicone surrounding the braided polyester woven reenforcement. This is equivalent to the proprietary polymer surrounding the superalloy braided monofilament metal reenforcement of the Schneider Stent.
Both Stents are supplied with Stent insertion accessories, which allow for placement of the Stent into the body.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 7 2001

Ms. Karenann J. Brozowski
Group Regulatory Affairs Director
Rusch International
Tall Pines Park
Jaffrey, NH 03452

Re: K013266
Trade/Device Name: Rusch Polyflex Stent Kit
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: September 27, 2001
Received: October 01, 2001

Dear Ms. Brozowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013266

Device Name: Rüsch Polyflex Stent Kit

Indications For Use:

Compression or strictures due to tumors (trachea and main bronchus)
Stenosis of the central airways (such as trachea and main bronchus)
Tracheo Esophageal fistula
Airway complications such as anastomosis and stenosis

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1–2–96)

Susan Walk

(Division Sign-Off)
Division of [illegible] Restorative
and Neurological Devices

510(k) Number K013266